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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/816,756 | 03/24/2001 | Bruce J. Mayer | 883933.0062 (UCON-154) | 4784 |

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EXAMINER

WESSENDORF, TERESA D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1639

DATE MAILED: 04/18/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/816,756 | Applicant(s) MAYER, BRUCE J. | |
| | Examiner T. D. Wessendorf | Art Unit 1639 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
 4a) Of the above claim(s) 1-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election of Group IX in Paper No. 8 (claims 28-29) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

During a telephone conversation with Evelyn Sommer on 4/2/03 a provisional election was made without traverse to prosecute the species of SH3 homology, recited in claim 2. Affirmation of this election must be made by applicant in replying to this Office action.

Status of Claims

Claims 28-29 are under examination.

Claims 1-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

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Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Src as the modular protein binding domain(MPBD), does not reasonably provide enablement for a method employing any kind of modular protein binding domain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of enabling disclosure is not commensurate in scope with the broad claimed method employing any or all kinds

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of MPBD. The specification recites generalizations as to the effect of the method using different MPBD. The exemplification is limited to a single MPBD, src. It is not apparent from the single embodied example its applicability or extrapolation to all or any type of MPBD. Hurst (Protein Profile), page 106, col. 2, discloses that MPBD (i.e., transcription factor) show different activities depending which other protein it is dimerized to, as illustrated by the complicated regulatory circuit of Jun, JunB, ATF3 and Fos. These factors may repress depending on the context of their promoter binding site. Other bZIP proteins have different splice variants which demonstrate different activities from one another. These activities of bZIP proteins are very varied. Consequently, the role of the leucine zipper as a generalized protein-protein interaction domain must be investigated very carefully for each proteins (page 109, col. 2). To date sequences of a mammalian gene e.g., chicken or mouse have not been completed but have been considered as distinct genes at the present time. Because of unpredictability in the art as discussed by Hurst, one would have not deemed applicants' disclosure as enabling for the broad claimed method. Other factors to be considered in a determination of undue experimentation are disclosed in *In re Wands*, (U.S.P.Q. 2d 1400 (CAFC 1988)).

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1). The amount of direction or guidance presented: The specification fails to give adequate direction and guidance in how to readily go about determining which MPBD can be used in the assay that imparts any biological activity in the protein-protein interaction.

2). The presence or absence of working examples: The specification provides assay for a single MPBD, src. It fails to provide working examples for any gene construct encoding any kind of MPBD that would result in any change in the biological activity to determine the activity of the protein-protein interaction.

3). The breadth of the claims: The breadth of the claims encompasses a large genes encoding MPBD, not to mention the degeneracy of the codons. It is well known in the art that it is often difficult to know what the expression level of specific peptides or peptide fusions is; in many cases, even an average measure of expression level is difficult to obtain. The diversity of the inserts is not easily estimated. It may be for example, that only a small subset of possible peptide sequences are presented efficiently by a particular expression system. And, it is not always easy to follow the expression of peptides in particular cells; for example, to know whether or not a specific cell is expressing a member of the insert.

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4). The state of the prior art: The state of the prior art is such that while techniques or the expression of determinants on the surface exist only for the well-studied cells, genes and vectors. However, limitations are known to exist. For example, M13 gene VI, VII, and IX proteins are not processed after translation. The routes by which these proteins are assembled into the phage have not been reported. These proteins are necessary for normal morphogenesis and infectivity of the phage. Whether these molecules (gene VI protein, gene VII protein and gene IX protein) attach themselves to the phage from the cytoplasm from the periplasms or from within the lipid bilayer is not known.

Applicants' specification reasonably would not have assured persons skilled in the art that the numerous undefined variables could be assayed for protein-protein interaction without undue experimentation. Applicants do not adequately enable persons skilled in the art to readily determine such. Applicants need not guarantee the success of the full scope of the claimed invention. However, skilled artisans are provided with little assurance of success.

[A claim drawn to an assay for the presence of the protein-protein reactions between the fusion of src with heterodimers Win-Zip A1 and B1 will obviate this rejection.]

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 28 is indefinite as to the type of assay being claimed. The body of the claim recites looking at any change in the biological activity of the protein-protein interactions. It is not clear as to what the "looking" step entails. Furthermore, it is not clear as to the step of comparison with the base line control. [Cf. with the Example at page 18]. The preamble is at odds with the body of the claim. The preamble recites a method while the body recites the non-elected compound. Thus, it is not clear as to the further limitation of the method. It is suggested that the claim be rewritten similar to page 6, lines 10-21 of the specification.

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B. Claim 29 is confusing as to the transformation of the control, especially in the absence of positive support or showing in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-29 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Michnick et al (US 6,270,964) or applicants' disclosure of known prior art [page 9, lines 12-17 of the instant disclosure.]

Michnick discloses at col. 7, lines 3-27 a method of testing for biomolecular interactions associated with binding of two protein-protein interacting domains from a second or third molecule comprising creating a fusion of a first fragment of a first molecule whose fragments can exhibit a detectable activity when associated and a first protein-protein interacting domain; creating a fusion of a second fragment of said first molecule and a second protein-protein interacting domain that can bind said first protein-protein interacting domain; allowing the fusions of (1) and (2) to contact each other; and testing for said activity. See further Fig. 1 and Fig. 6; RESULTS at col. 12.

Applicants state that WIN-ZIP synthetic zippers first described by Michnick.... are employed..." The claimed Win-Zip A1

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and B1 would inherently be present in the protein GNC4 of Michnick. As applicants recognized Michnick discloses these heterodimers, WiZip A1 and B1. Furthermore, the enzyme DHFR of Michnick would be considered as a modular protein binding domain or would at least inherently, if not obviously, contain a protein binding domain.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tripet et al discloses a de novo-designed coiled-coil heterodimerization.

[Claims drawn to an assay with a fusion containing the elected species, SH3, is free of prior art.]

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned

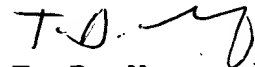
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are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
April 16, 2003